REMARKS

Claims 1-57 and 60-71 are pending in the current application. Claims 1-8, 13-19, 45-47 and 51-55 were examined. Claims 9-12, 20-44 and 48-50 were withdrawn by the Examiner. Applicants request clarity of the status of Claims 56-57 and 60-71. Claims 56-57 and 60-71 were not included in the list of claims withdrawn on page 3 of the Office Action, although they were included in the list of nonelected Groups. The Examiner has not indicated the withdrawn claims on the Office Action Summary, PTOL-326.

Double Patenting

Claims 1-8, 13-19, 45-47, 51-53, and 55 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 19-45, 52-61 and 93-113 of copending Application No. 10/523,117.

Applicants respectfully request that this rejection be held in abeyance until the claims of one of the patent applications is found to be allowable.

Claim Rejections – 35 USC § 102

Claims 1-8, 13-19, 45, 47, and 51-55 are novel over Hermand et al.

Claims 1-8, 13-19, 45, 47, and 51-55 were rejected under 35 U.S.C. 102(a) over Hermand *et al.* (WO 02/30458A1). Applicants respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). M.P.E.P. § 2131. Furthermore, " '[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test." M.P.E.P. § 2131. Additionally, "[w]hen the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference

and combine them ... anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex. Parte A,* 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated." M.P.E.P. § 2131.02 (A).

Hermand *et al.* do not teach an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria, as recited in Applicants' independent Claim 1.

Hermand et al. relates to adjuvant compositions that comprise a Yersinia adhesion protein which is suitable to be used in vaccines and further provides vaccines comprising the adjuvants and an antigen or an antigenic composition. (For example, abstract; page 1, lines 1-13; page 8, lines 17-21).

Hermand *et al.* do not teach a vaccine composition comprising "Neisserial antigens Hsf-like and TbpA and TbpB (Examples and claim 9)" as suggested by the Examiner (page 5, final paragraph, of the Office Action). Instead, each of the Examples in Hermand *et al.* relates to "a model antigen, the lipided outer surface protein A (L-OspA) from *B. burgdorferi*" (page 29, line 7-8) or TT as an antigen. (Examples). Claim 9 recites a vaccine composition comprising an adjuvant (as recited in claims 1-5) further comprising an antigen and an antigen composition (as recited in claims 6-8), wherein said antigen is selected from the group consisting of: "Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Heapatitis A, B, C or E, Respiratory Syncytial virus, human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Enterotoxic E. coli, Campylobacter, Streptococcus, Moraxella, Mycoplasma, Mycobacteria, Haemophilus, Plasmodium or Toxoplasma, Stanworth decapeptide; or Tumour associated antigens (TAA), MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH, CEA, PSA, PSMA, PAP, prostase, KSA, tyrosinase or PRAME." (emphasis added). Neither the Examples nor Claim 9 teaches a vaccine composition comprising antigens Hsf-like and TbpA and TbpB.

Applicants request that the Examiner point out with particularity where Hermand *et al.* teach a single immunogenic composition comprising Applicants' claimed combination of antigens. Applicants submit that the Examiner has merely chosen Applicants' claimed antigens (Hsf-like and Tbp) using hindsight, impermissibly guided by Applicants' own specification. The Examiner has selected, from pages of individually listed viral, bacterial, parasitic and tumor antigens, (pages 12-19), the antigens taught by the present specification. Hermand *et al.* at most suggest that any one of these listed antigens may be combined with the claimed adjuvant. This long list of pathogens and antigens is not sufficiently limited to enable one of ordinary skill in the art to at once envisage Applicant's claimed combination of antigens.

Hermand *et al.* fail to teach each and every element as set forth in independent Claim 1. They do not teach an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria. One of ordinary skill in the art could not 'at once envisage' Applicants' claimed combination of antigens based on the disclosure of Hermand *et al.* The identical invention is not shown in Hermand *et al.*

Applicants respectfully request that this rejection be withdrawn.

Claims 1-8, 13-19, 45-47 and 51-55 are novel over Berthet et al.

Claims 1-8, 13-19, 45-47 and 51-55 were rejected under 35 U.S.C. 102(b) over Berthet *et al.* (WO2001/09350). Applicants respectfully traverse this rejection.

Berthet *et al.* do not teach an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria, as recited in Applicants' independent Claim 1.

In contrast, Berthet *et al.* relates to "an immuno-protective and non-toxic Gram-negative bleb vaccine suitable for paediatric use....The blebs of the invention are improved by one or more genetic changes to the chromosome of the bacterium, including up-regulation of protective antigens, down-regulation of immunodominant

non-protective antigens, and detoxification of the Lipid A moiety of LPS." (Abstract, emphasis added). (Acknowledged by the Examiner on page 7 of the Office Action). Each of the methods described by Berthet *et al.* relates to methods to effectuate changes in the antigen expression in blebs.

Berthet *et al.* do not describe each and every element as set forth in Applicants' independent Claim 1. Berthet *et al.* do not teach an immunogenic composition comprising isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria.

Applicants respectfully request that this rejection be withdrawn.

Citation of Relevant Art

The Examiner has quoted the Abstract of Robinson *et al.* (U.S. Application 2003/0215469) and stated that it is relevant art. However, Robinson *et al.* relates to a composition comprising N. meningitidis outer membrane vesicles, wherein said outer membrane vesicles are enriched with at least one antigenic component.

Applicants' claimed invention relates to isolated antigens and fragments thereof, not outer membrane vesicles. Specifically, Applicants' claimed invention relates to an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria, as recited in independent Claim 1.

Applicants submit that Robinson *et al.* is not relevant art.

CONCLUSION

Should any outstanding issues remain, the Examiner is encouraged to contact Applicants' undersigned representative.

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